

Onshoring Drug Manufacturing Is Critical, But Not Easy

Steve Brozak is the Managing Partner and President of WBB Securities, LLC. In 2013, Dr. Brozak was selected as a top analyst in the pharmaceuticals sector by the StarMine/*Financial Times* Industry Analyst Awards. He also was named to *The Wall Street Journal's* “Best on the Street” list in the category of medical equipment and supplies. Earlier, Dr. Brozak worked in finance at Alex. Brown & Sons, Cowen & Company, Dean Witter and Salomon Brothers. Dr. Brozak has written for *Nature*, *The British Medical Journal* and *Brain Stimulation*. He is also a contributor to *Forbes* and ABC News. He received a B.A. degree and an MBA from Columbia University and a Doctorate in Medical

Humanities — DMH — from Drew University. He served in the United States Marine Corps, retiring as a lieutenant colonel.

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TWST: How is your coverage weathering the tariff storm?

Dr. Brozak: Our life sciences dedicated franchise, WBB Securities, is the busiest we've ever been in the history of the firm, and the life sciences investment field is also the busiest I've seen in almost 40 years, but not necessarily in a good way.

TWST: Can you give us a look at your current role and your specific coverage of biopharma subsectors.

Dr. Brozak: Being a boutique shop is one of our great advantages, even though sometimes there are more irons in the fire than we are comfortable with. We do research, of course, we do advisory, and we raise funds and manage assets. And in this time of uncertainty, every part of what we do is in significant demand. So we must prioritize our efforts and, as everyone likes to refer to, to understand what the big picture is in the long game.

TWST: And do you look at both big pharma and small health care companies?

Dr. Brozak: We cover the entire gamut. And the proverbial truth is that today's small biotech company has the chance of being tomorrow's next large pharmaceutical or biotech company.

As a reminder, I worked on the initial public offering for **Celgene Corporation** when it was a spinoff from **Hoechst Celanese**. So, undertaking that effort was an example of being able to understand conceptually what platform **Celgene** had at the time. The same ability to understand the underlying technology applies for other companies like, for example, **Alexion Pharmaceuticals**.

And today, to some degree, a lot of companies, unfortunately, probably most companies in the life sciences field, are not prepared for what they need to do next. And that means that you have opportunities if you understand what are the requirements for both investing and positive product and company outcomes.

TWST: Are there any specific sectors within life sciences, or subsectors, that have been most resilient to the tariff volatility?

Dr. Brozak: No, none and I did write about this a little while back in *Forbes* (<https://www.forbes.com/sites/stephenbrozak/2025/03/04/as-tariffs-begin-what-will-they-do-to-drug-prices-and-availability/>). They are all problematic — from generic manufacturers to the most specialized biotech powerhouses. And the reason is simply that we have several issues around transparency within HHS, specifically around FDA, that need to be resolved. Now, there's nothing wrong with changing the rules, but you must make sure that the rules for approval, the rules for reimbursement, are “out loud” and that everyone can adjust.

TWST: In the *Forbes* article you wrote, “Generic drugs, which account for almost 90% of all prescriptions dispensed in the U.S., will particularly be vulnerable to these tariffs.” Why so?

Dr. Brozak: For most of these drugs, the Active Pharmaceutical Ingredients, the API, and even the inert materials are made in China. Even if the pills are produced in India, the precursors still come from China. So then the question becomes, what kind of tariff do you affix on these products? Do you treat them as precursors, or as developed products, and how do you judge and assess which they are? That's the critical issue. How do you go out and figure what the charges are going to be?

And in terms of onshoring, which by the way, I do advocate for, we don't have the level of expertise needed today or even the facilities to actually make these drugs in the United States. We've outsourced most manufacturing for these drugs given the Medicare Part D requirements that specify how different drugs will be made and their profitability to the large pharmaceutical manufacturers.

So onshore manufacturing is not just a laudable goal, it's a critical goal, but you must understand the nature of the beast.

TWST: Why is that? Why can't we do it? Why do we manufacture mostly in China? Don't we have the brains, or particular metals, or technology?

Dr. Brozak: Well, I think it started with some pharma consulting analysis saying that pharmaceutical companies can make so much more from branded products covered by intellectual property rights.

So right off the bat, there was a situation where companies had to decide to make something that's critically needed but with not a high enough margin, or to make a therapeutic that requires fewer financial resources and, well, may not be as needed, but with a high profit margin. That was the first arrow in the quiver of the outsourcing movement.

The second one was that a lot of these products, like penicillin, are very dirty products to manufacture. There are a lot of waste materials and contamination issues that the EPA justifiably has concerns with. Unfortunately, in places outside of the United States, these are not concerns. So businesses can operate there in a different regulatory environment.

As a result, and this is the strange part, even if you apply significant tariffs, 100% plus, it's still cheaper to make and import these types of products into the United States than make them here. And I'm talking about critically needed products.

TWST: Right now China's looking at something like 140% tariffs. And if that happens, do you think the U.S. will start manufacturing and creating drugs at home, if it becomes cheaper domestically?

Dr. Brozak: There are three things to note: Number one, the Chinese understand geo-global politics like no other country in the world. So you must understand that they are the preeminent long-game players. So make sure that you understand not the second, but the third, fourth and fifth outcomes for any decision on tariffs.

Number two, even if we were to start a development plan for, let's say, for generics, it would take between five and 10 years to create new facilities based on current requirements and then these facilities will need to be staffed, which is another challenge. In the *Forbes* piece, I wrote about how the prospect of sending people to Mars is probably simpler than returning this type of manufacturing to the United States.

And finally, who's going to buy the products we're talking about? Even when you have the differentials that a tariff provides, you still can't get the products cheaply enough without direct government purchasing, and that's a kettle of fish that I don't know how to weigh in on. In short, it would require a lot more work than has been done so far.

TWST: Who is going to weather the storm for these increased prices for biopharmaceuticals? Will it be covered? Or will patients have to pay?

Dr. Brozak: Well, among the likely two situations you're talking about are, number one, you'll see shortages. Why? We only need to go back to COVID to remember that there were shortages in basic products like toilet paper and some canned goods because of hoarding. In this case, who will be doing the hoarding? It's obviously not going to be the individuals at home, but hospital systems or purchasing wholesalers.

So ultimately, the people who will pay will unfortunately be those people who critically need the product. For example, when you're talking about an antibiotic that, after the current copay, the patient pays \$2.75, it's likely to see a price of \$12.75. And that might not seem like much of an increase, but if you're talking about every day, for patients who in some cases take 10 or 12 drugs a month, that's an unaffordable situation, especially if they're on a fixed budget.

TWST: That's a very scary scenario, especially given the aging population in our country. Let's look beyond tariffs. Any other significant changes under Trump and/or with RFK taking the reins in health care?

Dr. Brozak: I don't believe RFK's opponents took the right tack in dealing with him and understanding him. I think they focused on criticizing him and some of his statements instead of reaching out and saying, "how can we work with you?"

Nobody, even his most strident critics, would acknowledge that the current health care infrastructure system that we have works. No one. So instead of sitting down with him and saying, "OK, give me your ideas," they were literally criticizing everything and all the people around him, without even trying to provide any input.

Everyone's human. With that type of criticism, with the vitriol that was sent around, there is no discussion any longer. It becomes a pretty vicious back and forth. And it doesn't do any good to criticize RFK Jr., Oz, or any of the rest, on the front page of *The Washington Post* or *The New York Times*, because they're still the ones that are in charge and making the decisions. Instead, it makes sense to offer options. That's what we really need to see next.

TWST: There was a lot of pushback to RFK Jr.'s views on vaccines. Speaking of which, where are most vaccines produced and manufactured?

Dr. Brozak: Although it's not as problematic on the vaccine front as it is on other fronts, there are supply chains on vaccines that frankly are from all over the world and the fill-finish production is all over the world as well — fill-finish is the last step in the pharmaceutical manufacturing process where the product is inserted into a vial. So, let's just say that it's dependent on the vaccines themselves and their price and also on who the manufacturers are.

TWST: So, none of this manufacturing takes place domestically?

Dr. Brozak: Some of it does take place in the U.S. I'm not going to tell you it doesn't; probably more for vaccines than a lot of other products. But some of the manufacturing facilities are overseas, and the fill-finish certainly is done all over the world.

TWST: Some say that we've already fallen into a recession. If that's true, or if we eventually do go into a recession, how will it impact these life science companies?

Dr. Brozak: The life sciences companies with revenue will see a hit to their bottom line. Why? Typically in a recession, you have people who become unemployed, and insurance is directly equated with employment. If you don't have medical insurance to get health care, you're certainly not going to buy products. So that's the first issue.

The second issue would be that it depends on the type of recession. If we're talking about the garden variety recession where prices are fixed, that is manageable. But if we have a stagnant inflationary situation, you could see people who are on fixed incomes now unable to buy the therapeutics they need. And that's the worst of all worlds.

So these are highly unusual times and the solutions are obviously going to be far different than anything we've seen before.

TWST: Do you see any notable technological advances making a difference to current or upcoming health issues? Is AI making a difference?

Dr. Brozak: I wrote two pieces on AI for Forbes. I believe that AI plays a critical role in the life sciences process, but it's different than people think. It is not about finding new molecules and wonder drugs via some supercomputer. That's too much to expect.

Typically, what we see for AI in health care is the translation of trial results. Especially within large pharmaceutical companies, they have acquired hundreds and hundreds of different programs that analyze trial results. In some cases, when they have a trial result, but part of the company may not understand the trial result, that's where they need AI to translate the different formats so they can be understood and synchronized in their outcomes.

In other cases, AI can help develop drugs. I wrote a piece about how fentanyl could be manufactured without restricted precursor detection using new AI mechanisms. These are completely different AI uses than people expect.

I think that with AI, the outcomes we will achieve in the life sciences will be very different than what we expect. And certainly, it's not what Silicon Valley is working on, and what a lot of our biotech VCs are investing in.

TWST: What are some life sciences companies, specific names, that you would recommend?

Dr. Brozak: One company that I've been talking about for years is a company called **Omeros** (NASDAQ:OMER). They have a product for which they just resubmitted a Biologics License Application — BLA. It's called narsoplimab and it regulates the lectin pathway, which is the inflammatory part of the complement system. That's a mouthful, isn't it?

What our complement system does is defend against infection or injury, which is aided by inflammation. But sometimes the inflammatory system overreacts and causes more harm than good. And the **Omeros** product works by reducing that overexpression of inflammation.

The indication for which **Omeros** submitted approval is called stem cell TA-TMA. It is a life-threatening inflammatory event that is not resolved in children and adults who have undergone stem cell transplants.

Omeros has resubmitted for narsoplimab to treat TA-TMA, and it looks like they're on the verge of an approval.

The important consideration is that narsoplimab isn't just for one critical indication. It can also help patients experiencing a life-threatening inflammatory cascade caused by other events, like SARS-CoV-2.

We think that that is something people will look at and say, "Wow, you know, we never really understood inflammation." I believe that this is one product area that **Omeros** has a lock on, and people should look at the company and the product very seriously.

TWST: So is that something that people who are not even very ill, but would just like more protection against lectins can use?

Dr. Brozak: The lectin pathway, the classical pathway — which triggers the body's response to infections — and the alternative pathway — which is the reinforcement loop — are more important than most really know, because when you're talking about influenza or SARS-CoV-2 or frankly any other kind of inflammation, that's the stuff that you have to really seriously worry about. And I think that that's why this is a platform.

TWST: And where was it created? And where is it manufactured?

Dr. Brozak: The company is out of Seattle. The manufacturing is overseas. The fill-finish, I believe, is done in Germany, but right now, they have more than enough doses here in the United States. So there shouldn't be any problems there at all.

TWST: Any other names that you like?

Dr. Brozak: Yes. There's one that has been seen as significant. The company is called **Sarepta Therapeutics** (NASDAQ:SRPT). They're out of Cambridge, Massachusetts. And they're one of the original ultra-orphan indication companies. They have products for young boys who have specific types of Duchenne muscular dystrophy. Their four products are lifesaving for those boys who have Duchenne Muscular Dystrophy by correcting the gene defects that are the cause of their disease.

And I think that **Sarepta** has started a process where they're building themselves into a next-generation type of company that advocates for science and orphan diseases.

TWST: Do you think that can eventually be used for adults?

Dr. Brozak: Right now they are for Duchenne muscular dystrophy. The problem specifically affects young boys. So, most of the **Sarepta** products need to be taken throughout their lives, but they will allow for longer lifespans and better quality of life. So this is the substance in gene therapy that people really are fascinated by, and justifiably so.

There's one other name. The company is called **Cidara** (NASDAQ:CDTX). I've talked about them before. They have an antiviral program that specifically deals with influenza. And we think it's critically important that this type of approach, this type of company, needs to be husbanded, resourced.

Why? Because one of the unpopular vaccine topics has been how well influenza vaccines do or don't work? And the answer is, it depends on the match. As a result, a lot of vaccine technology, and a lot of vaccines have lost their popularity; belief in them has fallen by the wayside.

No one believes in vaccines more than I do. They have saved more lives than all other therapies combined. However, they are not a be all and end all when it comes to a disease like influenza.

Cidara and their platform is a strong one in specifically shutting down all different influenza viruses. They've had quite a bit of support from venture capitalists and some from government as well. This is the type of technology we should look at and understand better. So, I end with that last company.

Now in terms of the outlook, I would say that for large pharmaceutical companies, this will be a problem because they've

been operating with a focus on revenue and only revenue. It's going to be a whole lot harder to get that revenue into the future, and the discounting that will take place will be significant.

So my thoughts for investors who look at this space should be that they need to understand products that are based on platforms. And those platforms are the saving grace, because if a product does have a platform and an unusual but positive outcome is observed, the companies can always pivot and add. And in pivoting, they can go out there and do what's critically important, follow the science to provide for the outcomes that we all hope and expect to see in the life sciences industry.

TWST: Thank you. (VSB)

Note: Opinions and recommendations are as of 4/11/25.

Steve Brozak

Managing Partner & President

WBB Securities, LLC

(858) 592-9901

www.wbbsec.com

email: contact@wbbsec.com

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